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LOCAL COVERAGE DETERMINATIONS CREATE INCONSISTENCY IN MEDICARE COVERAGE

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EXECUTIVE SUMMARY: Local Coverage Determinations Create Inconsistency in Medicare Coverage
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WHY WE DID THIS STUDY

Medicare administrative contractors (MACs) and the Centers for Medicare & Medicaid Services (CMS) sometimes develop policies to limit Medicare coverage of specific items and services. MACs issue local coverage determinations (LCDs) that limit coverage for a particular item or service in their jurisdictions only. This can lead to State-by-State variation in Medicare coverage for similar items and services. Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) calls for a plan to evaluate new LCDs to determine which should be adopted nationally and to what extent greater consistency can be achieved among LCDs. This study determined the variation in coverage of Part B items and services as a result of LCDs and assessed CMS's efforts to evaluate LCDs for national coverage as required by the MMA.

HOW WE DID THIS STUDY

We analyzed a 1-week period within the Medicare Coverage Database to determine the LCD-caused variation in coverage of Part B items and services. We also used data from the National Claims History and the Enrollment Database to test for relationships between cost and utilization of items and services and presence or absence of an LCD. From CMS, we requested documents created by its 731 Advisory Group and LCD Writers' Group. Finally, we interviewed CMS staff and MAC staff to further our understanding of actions CMS has taken in response to Section 731 of the MMA.

WHAT WE FOUND

In October 2011, over half of Part B procedure codes were subject to an LCD in one or more States. The presence of these LCDs was unrelated to the cost and utilization of items and services. Furthermore, LCDs limited coverage for these items and services differently across States. LCDs also defined similar clinical topics inconsistently. Finally, CMS has taken steps to increase consistency among LCDs, but it lacks a plan to evaluate new LCDs for national coverage as called for by the MMA.

WHAT WE RECOMMEND

We recommend that CMS establish a plan to evaluate new LCD topics for national coverage consistent with MMA requirements. We also recommend that CMS continue efforts to increase consistency among existing LCDs. Finally, we recommend that CMS consider requiring MACs to jointly develop a single set of coverage policies. CMS concurred with all of our recommendations.

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OBJECTIVES

1. To determine the extent to which Part B items and services are subject to Local Coverage Determinations (LCDs).
2. To determine the variation in coverage of Part B items and services as a result of LCDs.
3. To assess the Centers for Medicare & Medicaid Services' (CMS) efforts to evaluate LCDs for national coverage as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

BACKGROUND

Medicare coverage exists for most items and services without the need for individual coverage policies. To be covered by Medicare, an item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body part.[1] If an item or service also falls under a Medicare benefit category and can be reimbursed on the basis of an existing procedure code, Medicare may cover it without an individual coverage policy for that item or service.

However, Medicare claims processing contractors and CMS sometimes develop coverage policies to limit Medicare coverage of specific items and services. They may do so by describing coverage with restrictions on the basis of certain clinical conditions, prerequisite treatments, and other factors. Each coverage policy speaks to a clinical topic and may address one or more types of service such as drugs; evaluation and management; imaging; medical procedures; and tests. Contractors issue local policies—called LCDs—that apply to the States in their jurisdictions. CMS develops national policies—called national coverage determinations (NCDs)—that apply to all beneficiaries across the country.

Overview of LCDs

An LCD is a determination by a Medicare claims processing contractor that defines coverage for a particular service in the contractor's jurisdiction.[2] LCDs must be consistent with all statutes; rulings; regulations; and national policies for coverage, payment, and coding. LCDs may address a specific clinical topic using procedure codes to define one or more treatments and using diagnostic codes to describe the clinical indications that would make the treatment(s) reasonable and

[1] Social Security Act § 1862(a)(1)(A), 42 U.S.C. § 1395y(a)(1)(A).
[2] Ibid.

necessary.[3] For example, an LCD may limit coverage of an item or service to specific diagnoses, or it may prohibit coverage of an item or service completely. The coverage policy created by an LCD is applicable only in States within a contractor's jurisdiction.

CMS's *Medicare Program Integrity Manual* instructs contractors on how to develop LCDs.[4] The process includes several mechanisms for local stakeholder input, including notice and comment periods for new LCDs and State-based physician advisory committees to provide formal input on LCDs. Each administrative contractor has a physician who, as the contractor's medical director, helps develop and manage LCDs in the contractor's jurisdiction.

Contractors create an LCD when they identify the need for one or when they accept requests from external parties (e.g., beneficiaries, providers, or manufacturers). Contractors identify the need for an LCD when they determine that an item or service should not be covered under certain circumstances and they wish to establish automated checks of claims for the item or service.[5] They may also develop LCDs when a problem demonstrates a significant risk to the Medicare trust fund or when a contractor detects overutilization or misuse of items or services.[6]

LCDs are publicly available in the Medicare Coverage Database on the CMS Web site. Physicians, beneficiaries, and others may search the database for LCDs by procedure code, diagnosis code, clinical topic, or date. In August 2013, CMS's Web site listed over 1,700 active LCDs in the Medicare Coverage Database.[7]

Overview of NCDs

An NCD is a determination that defines coverage for a particular clinical topic nationwide. An NCD takes precedence over any LCDs that may exist on the same clinical topic. NCDs generally outline the conditions for which an item or service is covered or not covered.[8] Like LCDs, NCDs address a specific clinical topic. However, unlike LCDs, NCDs are developed by CMS under a centralized process. CMS may develop an NCD in response to internally generated review or in response to a request

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[3] *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 13, § 13.5.2.

[4] *Medicare Program Integrity Manual*, Pub. No. 100-08, ch 13.

[5] Automated reviews, or "edits," are put in place to prevent payment for noncovered, incorrectly coded, or inappropriately billed items and services. Most automated payment edits will be specific to a particular item or service.

[6] *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 13, § 13.4.

[7] LCDs active as of August 15, 2013, from an online search of the Medicare Coverage Database. Accessed at www.cms.gov on August 15, 2013.

[8] *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 13, § 13.1.1

from an external party. NCDs are publicly available in the Medicare Coverage Database. In August 2013, CMS's Web site listed over 300 active NCDs in this database.[9]

CMS occasionally posts announcements on its Web site of clinical topics that it will consider for an NCD. CMS identifies these clinical topics on the basis of its reviews and public input. Most recently, in November 2012, CMS published a list of 32 potential NCD topics, some of which are currently subject to an LCD in one or more contractor jurisdictions.[10]

Changes to Coverage Policy Development and Contractors

In 2003, two provisions of the MMA affected Medicare coverage policies. First, Section 731 called for a plan to evaluate new LCDs to determine which should be adopted nationally and the extent to which greater consistency could be achieved among LCDs.[11] Second, Section 911 made changes to the claims processing contractors, replacing Part A Fiscal Intermediaries (FIs) and Part B Carriers with new regional contractors called Medicare administrative contractors (MACs).[12]

CMS Efforts to Evaluate LCDs for National Coverage. To implement Section 731 of the MMA, in 2006 CMS added a section to the *Medicare Program Integrity Manual* to establish the 731 Advisory Group to review LCD topics for NCD consideration.[13] Therein, CMS also established a framework for contractors to refer new LCD topics to this advisory group. The framework includes evaluation criteria, time lines, and minimum specifications for a database to track LCD topics submitted for review.

Medicare Contractor Consolidation. Pursuant to Section 911 of the MMA, CMS began to shift from 51 State-based contractor jurisdictions to 15 multi-State MAC jurisdictions by awarding its first MAC contracts in 2006. CMS awarded a contract for each jurisdiction to a MAC that was responsible for processing both Medicare Part A and Part B claims within the States that fall within its jurisdiction. Furthermore, CMS required the MACs to determine which LCDs of the outgoing FIs and Carriers to keep, change, or retire based on the most clinically appropriate criteria before consolidating them into multi-State, jurisdiction-wide policies.

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[9] NCDs active as of August 15, 2013, from an online search of the Medicare Coverage Database. Accessed at www.cms.gov on August 15, 2013.

[10] Potential NCD Topics. Accessed at www.cms.gov on March 19, 2013.

[11] MMA, § 731.

[12] MMA, § 911.

[13] CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, Transmittal 147, Change Request 4233 (revising CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 13, § 13.14). Accessed at www.cms.gov on September 26, 2011.

By August 2013, CMS had transitioned all claims processing to MACs except for that of one Carrier. CMS plans to further consolidate the original 15 MAC jurisdictions into 10 MAC jurisdictions.

MedPAC and GAO Work on LCDs

In 2001, the Medicare Payment Advisory Commission (MedPAC) recommended that Medicare eliminate local policies because they add unnecessary complexity, inconsistency, and uncertainty to the program.[14] Similarly, in 2003, the Government Accountability Office (GAO) reported that the broad discretion given to contractors to make LCDs resulted in inequitable variations in coverage. GAO recommended that CMS replace LCDs with NCDs.[15]

METHODOLOGY

Scope

This study examined LCDs issued by MACs for Part B items and services performed by noninstitutional providers such as physicians, laboratories, and ambulatory surgical centers. Our review excluded LCDs for durable medical equipment. We focused on MAC-issued LCDs for Part B items and services because they are the most common type of LCD. Furthermore, we focused on LCDs that were in effect throughout the 1-week period of October 24, 2011, to October 30, 2011. Because the Medicare Coverage Database is updated weekly, a 1-week period provided us with a snapshot of coverage for items and services. MAC-issued LCDs for Part B items and services made up 1,131 (50 percent) of the 2,249 LCDs active during this time period. MAC jurisdictions covered 44 States and territories (States).[16] The claims processing workload in these States represents 80 percent of national claims processing volume. The remaining States were still under State-based contracts that CMS planned to combine during future MAC consolidation.

This study examined CMS's efforts to evaluate new LCDs for national coverage since June 2006, which is when it created the 731 Advisory Group.

[14] MedPAC, *Reducing Medicare Complexity and Regulatory Burden*, December 2001.

[15] GAO, *Medicare: Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities*, GAO-03-175, April 2003.

[16] These States include AL, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, KS, KY, MA, MD, ME, MO, MT, NC, ND, NE, NH, NJ, NM , NV, NY, OH, OK, PA, RI, SC, SD, TN, TX, UT, VA, VT, WV, and WY. American Samoa (AS), Commonwealth of the Northern Mariana Islands (CNMI), Guam (GU), Puerto Rico (PR), and the U.S. Virgin Islands (VI) are territories also under MAC jurisdictions.

Data Collection and Analysis

We used multiple data sources for this analysis: the Medicare Coverage Database; the National Claims History; the Enrollment Database; documents from CMS; and interviews of CMS and MAC staff.

Although LCDs affect coverage across entire MAC jurisdictions, we analyzed them with respect to States rather than jurisdictions because State boundaries are more familiar to most audiences.

Medicare Coverage Database. We downloaded the Medicare Coverage Database from CMS's Web site and analyzed it to determine the LCD-caused variation in coverage of Part B items and services. The Medicare Coverage Database contains the following data elements, among others, on each LCD:

- a variable that identifies the clinical topic of the LCD;
- variables that identify the type of contractor (e.g., MAC, Carrier, FI) that issued the LCD and the States within that contractor's jurisdiction;
- variables that show the effective dates of the LCD;
- fields for Health Care Procedure Coding System (HCPCS) codes and Current Procedural Terminology (CPT) codes to describe the items and services addressed by the LCD[17]; and
- fields for the International Classification of Diseases 9th Revision (ICD-9) diagnostic codes that represent the clinical indications for which the items and services addressed by the LCD are considered reasonable and necessary.

We identified 1,131 LCDs in the database that were issued by MACs for Part B items and services and were in effect throughout the 1-week period of our study.[18, 19] These LCDs addressed 540 clinical topics. The database enabled us to determine the extent to which procedure codes were subject to

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[17] **The five character codes and descriptions included in this report are obtained from Current Procedural Terminology (CPT®), copyright (2011) by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this report should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.**

[18] We identified MAC policies for Part B items and services by selecting policies issued by contractor type "9"—i.e., "MAC – Part B"—in the Medicare Coverage Database.

[19] Our final count of LCDs reflects a unique count of values of the "lcd_id" variable in the Medicare Coverage Database. The number of unique LCDs may be higher or lower; however, limitations of the Medicare Coverage Database prevent determining a definitive count of unique LCDs without reviewing the full text of every LCD. The count of LCDs does not affect analysis in this report because other variables enable us to determine the scope and reach of LCDs across States, items/services, and covered indications independent of the count of unique LCDs.

LCDs and to compare the diagnostic and procedure codes that LCDs used to define clinical topics.

National Claims History and the Enrollment Database. We used data from the 100-percent Physician-Supplier Standard Analytical File to determine the utilization of items and services during the 1-week period of LCDs we examined. We used the Enrollment Database to determine the numbers of fee-for-service Medicare beneficiaries in each State. We used these data, among other metrics, to compute allowed charges per procedure code and utilization rates per Medicare fee-for-service beneficiary.

We also used these data to test for relationships between cost and utilization of items and services and presence or absence of an LCD. To do so, we computed and evaluated a set of correlation coefficients that compared the following across the 7,500 procedure codes with allowed charges during our 1-week period of study: (1) average allowed charges and percentage of States with an LCD and (2) allowed units of services per 10,000 beneficiaries and percentage of States with an LCD.

In our analysis of procedure codes subject to LCDs, we used CPT codes defined by the AMA as Category III codes to identify new technology. CPT Category III codes are a set of temporary codes that allow data collection for emerging technology, services, and procedures. Category III codes can also represent established technology, services, and procedures being used in new applications that are not consistent with current medical practice.[20]

Documents from CMS. We requested documents created by the 731 Advisory Group and the LCD Writers' Group; the latter is a group that CMS later established to discuss the evidence for various clinical topics. We requested agendas and minutes of meetings and calls for both groups. We requested these documents to determine the results of CMS's efforts to evaluate LCDs for national coverage.

Interviews of CMS and MAC Staff. We conducted four interviews with CMS staff and with MAC staff, such as medical directors, to further our understanding of actions CMS has taken in response to Section 731 of the MMA and to identify other efforts CMS has taken to promote consistency among LCDs. Throughout the course of our study, we followed up with CMS and MAC staff by email when we had additional questions subsequent to these interviews.

[20] AMA, *Category III Codes*. Accessed at http://www.ama-assn.org/resources/doc/cpt/cptcat3codes.pdf on August 15, 2013.

Limitations

We analyzed coverage restrictions placed on items and services through MACs' use of ICD-9 diagnostic codes to describe "reasonable and necessary" provisions of LCDs. We did not analyze the Medicare Coverage Database to determine the extent to which MACs used other types of restrictions, such as requirements for prerequisite treatments, limits on frequency of treatments, requirements for provider qualifications, or requirements for beneficiary characteristics.

In addition to using the fields for ICD-9 codes in the Medicare Coverage Database, MACs sometimes also used narrative text in the body of the LCD and in separate attachments to describe the "reasonable and necessary" provisions for an item or service. Our review did not consider such narrative text.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

In October 2011, over half of Part B procedure codes were subject to an LCD in one or more States

LCDs had significant influence throughout Medicare's coverage of Part B items and services. LCDs defined coverage in one or more States for 59 percent of the 7,500 unique procedure codes billed to Part B during the 1-week period of our review. These codes covered a range of items and services including medical procedures, evaluation and management, imaging, drugs, and tests. Total billing subject to LCDs composed 26 percent of the $1.8 billion in allowed charges and 23 percent of 39.9 million allowed units of service that Part B MACs processed during the 1-week period of our review.

LCDs most often addressed medical procedures

Seventy-one percent of procedure codes for medical procedures were subject to an LCD in one or more States. Among others, these procedures include endoscopies, minor procedures related to the skin or musculoskeletal systems, and eye procedures. Furthermore, more than half (51 percent) of allowed units of service for medical procedures were subject to an LCD. This was nearly twice the percentage of allowed units of service subject to LCDs for all other types of items/services. (See Table 1.)

Table 1: Percentage of Procedure Codes and Allowed Units of Service Subject to LCDs by Type of Service

Type of Item/Service	Percentage of Procedure Codes Subject to LCDs	Percentage of Allowed Units of Service Subject to LCDs
Medical Procedures	71%	51%
Evaluation and Management Services	52%	8%
Imaging	47%	19%
Drugs	42%	28%
Tests	31%	19%
Other Items/Services*	74%	25%
Unclassified Items/Services*	28%	1%

*Other items/services and unclassified items/services together account for only 10 percent of total items/services.

Source: OIG analysis of CMS's Medicare Coverage Database, 2011.

The presence of LCDs was unrelated to the cost or utilization of Part B items and services

Although MACs may develop LCDs to prevent overutilization and the misuse of items and services, we found no correlation between the number of States with LCDs for items and services and the unit cost or utilization rate of those items and services. For example, 49 of the 100 most costly items and services—with an average unit cost ranging from $2,137 to $33,500—were not addressed by LCDs in any State. Additionally, 37 of the 100 most commonly used items and services—with usage rates ranging from 807 to 27 items and services per 10,000 beneficiaries—were not addressed by LCDs in any State. However, coverage for some of these items and services is defined in NCDs, the *Medicare Benefit Policy Manual*, or in statute, which may reduce or eliminate the need for LCDs.

LCDs limited coverage for these procedure codes differently across States

Medicare had at least two different coverage policies for the 59 percent of procedure codes subject to LCDs. All but two of these procedure codes were subject to one or more LCDs that limited coverage in some, but not all States. Thus, coverage for a given service may be restricted in one State where an LCD is in place and completely unrestricted in another State where no LCD is in place. The remaining two procedure codes were subject to LCDs in all States. However the LCDs for these procedures created different coverage policies that could vary from State to State.

MACs may have developed LCDs for these procedure codes to address situations in their local jurisdictions, including overuse or misuse of items or services. However, in addition to enabling MACs to address such problems, another outcome is that beneficiaries' access to items and services can depend on geography as much as their clinical indications.

LCDs prohibited coverage for some procedure codes—often those for new technology—in some States and not in others

LCDs prohibited coverage for 467 procedure codes for Part B items and services in one or more States. However, out of the 467 codes, 187 (40 percent) had allowed charges in one or more States where LCDs did not prohibit coverage. These allowed charges totaled $9.7 million during the 1-week period we reviewed, or about $500 million yearly. As a result, beneficiaries in some States did not have access to items and services that had significant use among beneficiaries in other States. For example, during the period of our review, an LCD prohibited coverage in three States for CPT code 86141 for high-sensitivity C-reactive protein

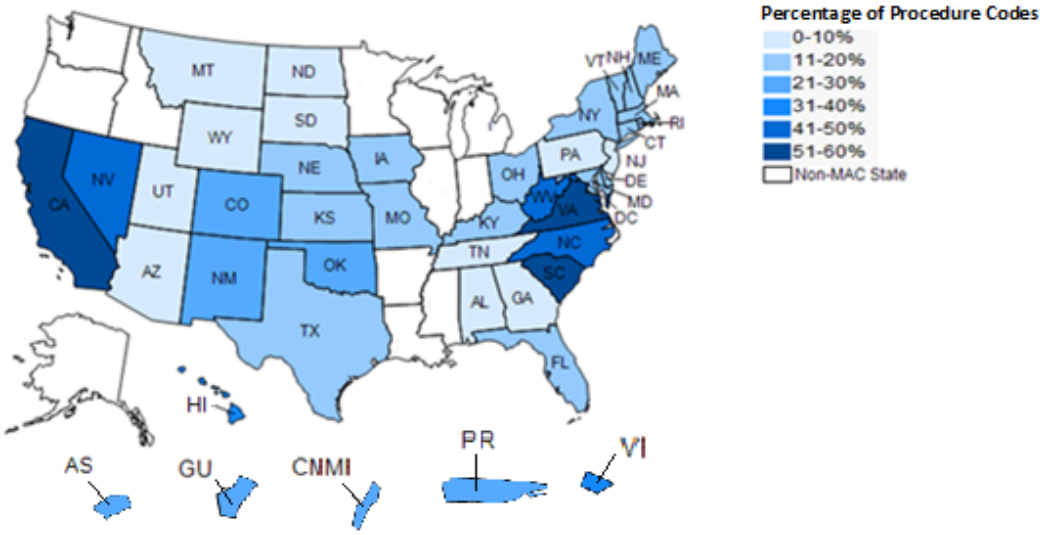
(hs-CRP) tests. At the same time, LCDs allowed coverage of hs-CRP tests in 20 other States, but only for beneficiaries with certain clinical indications. MACs did not issue any LCDs for hs-CRP tests in the remaining States, leaving coverage for it open without restriction.[21]

Out of the 467 procedure codes for which LCDs prohibited coverage in 1 or more States, 146, or nearly a third, were for new technology. Forty of these codes had allowed charges in one or more States totaling over $670,000 during the 1-week period we reviewed, or about $35 million yearly. Examples of the new-technology procedure codes for which LCDs prohibited coverage in one or more States during our review were the code for high dose rate electronic brachytherapy, a type of cancer treatment, and the code for insertion of a posterior spinous process distraction device, a type of spinal implant. Some MACs issued blanket LCDs prohibiting coverage of all procedure codes for new technology, stating that they considered new technology to be experimental and thus not covered by Medicare. Others did not issue blanket LCDs and addressed new technology for selected procedure codes or left coverage unrestricted.

LCDs limited coverage for many Part B items and services in some States and few items and services in others

LCDs affected coverage for over 50 percent of items and services in some States and as few as 5 percent of items and services in other States. In four States—California, North Carolina, South Carolina, and Virginia—50 percent or more of procedure codes were subject to an LCD. Conversely, in three States—Alabama, Georgia, and Tennessee—only 5 percent of procedure codes were subject to an LCD (See Figure 1).

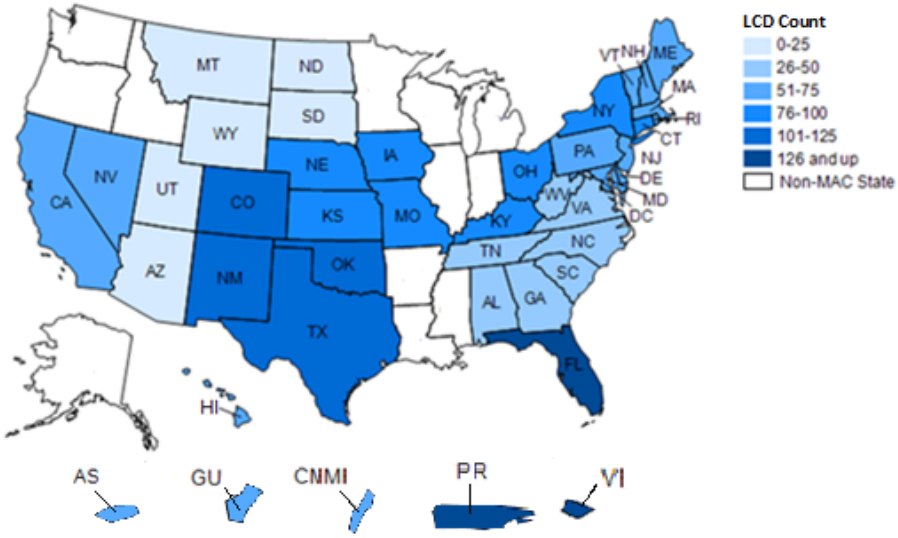
Figure 1: Percentage of Procedure Codes Subject to a Part B MAC LCD



[21] During the time of our review, Medicare did not have an NCD on hs-CRP tests, thus leaving coverage for hs-CRP tests open in States served by MACs without an LCD.

Additionally, LCDs were concentrated in several States. Over a fifth, or 236, of the 1,131 LCDs in effect during our review restricted coverage for items and services in only 3 States—Florida, Puerto Rico, and the Virgin Islands. These three States are all within the same MAC jurisdiction and one—Florida—contains two cities targeted by the Medicare Strike Force because of high levels of Medicare fraud. Conversely, some other States had as few as 25 LCDs that restricted coverage for items and services. Therefore, the likelihood that beneficiaries' items and services had coverage restrictions placed on them by LCDs varied widely by State (See Figure 2).

Figure 2: Count of MAC B LCDs per State



LCDs defined similar clinical topics inconsistently

Out of the 540 clinical topics addressed by LCDs, none were addressed by an LCD in every State—meaning that every clinical topic was addressed in some States but not others. LCDs address a specific clinical topic, such as interventional cardiology, by listing the procedure codes that define a particular treatment and the diagnostic codes that describe the covered indications for the treatment. Therefore, Medicare defines how and under what circumstances beneficiaries have access to certain treatments in some States (where an LCD exists), but not in others (where an LCD does not exist).

A total of 319 of the 540 clinical topics, or 59 percent, were addressed by more than one LCD; however, 134 were addressed inconsistently among LCDs. This means that different LCDs used different procedure and/or diagnostic codes to address the same clinical topic. One example is blepharoplasty—surgery to correct drooping eyelids that impair vision. At the time of our review, LCDs addressed blepharoplasty in 32 of the

44 States served by MACs. Although some codes were common across the LCDs, the LCDs used seven different lists of procedure codes and diagnostic codes to describe Medicare's coverage of blepharoplasty. In the remaining 12 States in our review, MACs had no LCD, leaving coverage for blepharoplasty open without restriction.[22]

CMS has taken steps to increase consistency among LCDs, but it lacks a plan to evaluate new LCDs for national coverage as called for by the MMA

CMS convenes a number of workgroups among the MACs that collaborate on discrete topics such as molecular diagnostic services and self-administered drugs. It also supports in-person meetings of the LCD Writers' Group, coordination calls among MAC medical directors, and a listserv for MAC medical directors to share information. Taken together, these activities have the potential to increase consistency among LCDs, but they do not represent a plan for evaluating new LCDs for national coverage.

To evaluate new LCDs for national coverage, CMS established the 731 Advisory Group and a review process in the *Medicare Program Integrity Manual*.[23] CMS defined (1) criteria that contractors' medical directors should use to evaluate topics to submit to the 731 Advisory group, (2) the role of the 731 Advisory Group, and (3) steps that CMS would take with respect to reviewing, tracking, and evaluating topics put forth for NCD consideration.

However, the 731 Advisory Group was either never convened or was disbanded when CMS shifted responsibility for LCDs within the agency. Thus, CMS was unable to quantify the results of the group or locate agendas and minutes of the group's meetings and calls. The 731 Advisory Group and the related framework for reviewing LCDs for national coverage remain in the *Medicare Program Integrity Manual*.

Finally, CMS was unable to fully quantify the results of the LCD Writers' Group and only provided examples of NCDs resulting from the group in its technical comments to our draft of this report. Although CMS was able to provide agendas from the group's meetings, it did not keep minutes of these meetings.

[22] During the time of our review, Medicare did not have an NCD on blepharoplasty, thus leaving coverage for blepharoplasty open in the 12 States served by MACs without an LCD. Those States were AL, AZ, CNMI, FL, GA, MT, ND, PR, SD, TN, UT, and WY.

[23] *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 13, § 13.14.

CONCLUSION AND RECOMMENDATIONS

Our review of a 1-week period in October 2011 has shown that LCDs create inconsistency in Medicare coverage policy. Although MACs may have written individual LCDs to address problems in their jurisdictions, collectively these LCDs create State-by-State disparities in Medicare beneficiaries' access to items and services.

As CMS consolidates the MACs to 10 jurisdictions, the premise of tying coverage to contractors' local jurisdictions becomes blurred. This is especially true when a single contractor has multiple jurisdictions, resulting in LCDs that affect coverage identically in a dozen or more States. In addition, the State-by-State differences in coverage created by LCDs are contrary to the growing practice of evidence-based medicine that eschews local variation.

Finally, Section 731 of the MMA called for a plan to evaluate new LCDs for national coverage and the extent to which greater consistency can be achieved among LCDs. We found that although CMS has taken steps to increase consistency among LCDs, it lacks a plan to evaluate new LCDs for national coverage as called for by the MMA.

Therefore, we recommend that CMS:

Establish a plan to evaluate new LCDs for national coverage consistent with MMA requirements

Without a planned approach to identifying new LCDs for national coverage, the effectiveness of CMS's efforts to increase consistency in coverage using NCDs is likely to remain limited. Furthermore, CMS will likely remain unable to quantify and evaluate its efforts to comply with Section 731 of the MMA.

In its *Medicare Program Integrity Manual*, CMS describes a process for reviewing new LCDs for national coverage, but the agency describes the process with respect to the 731 Advisory Group, which no longer exists.[24] CMS should revisit the process described in the *Medicare Program Integrity Manual* and use it as a starting point for a new process.

Continue efforts to increase consistency among existing LCDs

The workgroups that CMS convenes to address discrete coverage topics have the potential to increase consistency among existing LCDs. To build on these efforts, CMS could establish a process to identify clinical topics that are currently addressed differently by multiple LCDs and prioritize them for review for national coverage. In this inspection, we identified over 100 such topics.

[24] *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 13, § 13.14.

In August 2013, CMS published a notice in the *Federal Register* updating its process for opening, deciding, or reconsidering NCDs. As part of the notice's discussion on internally generated NCD review, CMS acknowledged that variation in LCDs for an item or service could prompt review for an NCD.[25] It also stated that variation in LCDs is not a de facto sign of inappropriate local policy. A process to identify and prioritize topics addressed by multiple LCDs would strengthen CMS's internally generated NCD review by offering clarity as to when variation among LCDs warrants review.

Consider requiring MACs to jointly develop a single set of coverage policies

Since 1993, CMS has encouraged Medicare's administrative contractors for durable medical equipment to coordinate their coverage policies across jurisdictions and in 2006, it required them to jointly develop and use a single set of coverage policies.[26, 27] Nonetheless, CMS still issues NCDs for durable medical equipment when it wishes to define coverage on its own initiative.

Similar coordination of coverage among the MACs would help simplify Medicare coverage and prevent Medicare beneficiaries' access to items and services from being tied to where they live. In establishing such coordination, CMS could retain elements of the current LCD process that allow for local input from beneficiaries, providers, and manufacturers. Eventually, a coordinated process among MACs could subsume CMS's NCD process, further simplifying Medicare coverage.

CMS may need to seek legislative authority to make these changes. We recognize that coordinating LCDs in the manner we suggest could slow down the LCD development process and have implications for MACs in handling appeals. However, the potential for stronger LCDs based on consensus among MAC medical directors on the effectiveness and medical necessity of items and services could outweigh these potential drawbacks. Finally, this coordination could ultimately lessen the workload of MACs and medical directors by enabling them to share resources and issue fewer LCDs overall.

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[25] *Medicare Program; Revised Process for Making National Coverage Determinations*, 78 Fed. Reg. 48167 (August 7, 2013).

[26] *Medicare Program; Durable Medical Equipment Regional Carrier (DMERC) Service Areas and Related Matters*, 69 Fed. Reg. 15755, 15757 (March 26, 2004).

[27] CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, Transmittal 165, Change Request 5301, dated October 6, 2006 (adding a new § 13.1.4 to ch. 13 of CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08).

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all three of our recommendations.

Regarding our first recommendation, which called for CMS to establish a plan to evaluate new LCDs for national coverage, CMS stated that it considers its workgroups and other initiatives as the plan it has implemented to comply with Section 731 of the MMA. However, we reiterate the importance that CMS's plan address criteria and procedures for reviewing, tracking, and evaluating NCD topics as it had originally set forth in the *Program Integrity Manual*. This would help ensure optimal use of MACs' resources and enable CMS to assess the effectiveness of its efforts to increase consistency in Medicare coverage policy.

Regarding our second recommendation, which called for CMS to continue efforts to increase consistency among existing LCDs, CMS identified its workgroups and a new MAC award fee metric to encourage MACs to collaborate. As we stated in our recommendation, a process for identifying and prioritizing topics addressed by multiple LCDs could strengthen these efforts as well as CMS's internally generated NCD review process.

In response to our third recommendation, CMS cited the barriers we mentioned in the recommendation as reasons why it has not required MACs to jointly develop a single set of coverage policies. CMS stated that it believes its workgroups and other initiatives will lead to increased LCD consistency. We maintain that pursuing a single set of coverage policies would simplify and strengthen Medicare coverage policy while lessening the administrative burden of LCDs.

For the text of CMS's comments, see Appendix A. CMS also provided technical comments, which we addressed as appropriate.

APPENDIX A
Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: NOV - 8 2013

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Local Coverage Determinations Create Inconsistency in Medicare Coverage Policy (OEI-01-11-00500)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above subject OIG draft report. The purpose of the report was to determine the variation in coverage of Part B items and services as a result of local coverage determinations (LCDs) and to assess CMS' efforts to evaluate LCDs for national coverage as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). OIG's objectives are to—(1) Determine the extent of Part B items and services subject to local coverage determinations (LCDs); (2) Determine the variation in coverage of Part B items and services as a result of LCDs; and (3) Assess CMS efforts to evaluate LCDs for national coverage as required by the MMA.

The Medicare program since its inception in 1965 reflects a legislative compromise that balanced central versus local authority. While Congress has explicitly granted local contractors the independent authority to make, within their jurisdictions, local coverage determinations (LCDs) under section1862(a)(1)(A) of the Social Security Act, CMS must balance this with executing the authority granted to the Secretary under section 1862(l)(5) to determine if, when appropriate, "greater consistency can be achieved among local coverage determinations."

The OIG recommendations and CMS responses are discussed below.

OIG Recommendation

The OIG recommends that CMS establish a plan to evaluate new LCDs for national coverage consistent with MMA requirements.

CMS Response

The CMS concurs and has implemented a plan as required by MMA section 731. After finding the 731 Advisory Workgroup to be unworkable and impractical in light of reductions in Contractor Medical Directors (CMDs) and CMS resources, we developed the current, and more efficient, paradigm of extensive engagement and collaboration with and among the Medicare

Administrative Contractors (MACs) with the goal of increasing consistency among LCDs in appropriate circumstances.

Specifically, CMS convenes face-to-face meetings with the CMDs multiple times a year to accomplish three primary objectives--(1) Collaborative learning on effective approaches to coverage; (2) Addressing at least one coverage decision topic in a unified manner at each meeting; and (3) Developing standardized processes and criteria for coverage decisions when appropriate.

The face-to-face meetings and other regularly occurring meetings facilitated by CMS provide a forum for the topical LCD Writers Workgroups that develop template LCDs. The template LCDs are presented to other CMDs for discussion and refinement. Each CMD makes a determination as to whether to present the template LCDs to the MAC's Part B Contractor Advisory Committees.

Also, CMS created a restricted listserv specifically for the CMDs who develop LCDs in an effort to simplify their communications and provide a forum for real time sharing of information on emerging and ongoing coverage issues. CMS will continue the efforts described above and will delete the reference to the 731 Advisory Workgroup in the Program Integrity Manual.

OIG Recommendation

The OIG recommends that CMS continue efforts to increase consistency among existing LCDs.

CMS Response

The CMS concurs. As stated in the response above, CMS has taken a number of steps to attempt to achieve more consistency among the MACs and the LCDs developed by them. Additionally, in order to measure and ensure increased collaboration among the MACs, we added language related to LCD collaboration to the MAC Award Fee metric. This award fee criterion measures the MAC's collaboration with other key stakeholders to the benefit of the Medicare program. The CMS plans to continue its current efforts to achieve greater LCD consistency as appropriate.

OIG Recommendation

The OIG recommends that CMS consider requiring MACs to jointly develop a single set of coverage policies.

CMS Response

The CMS concurs. We have considered requiring MACs to jointly develop a single set of coverage policies. However, as noted in the draft report, we have not done so due to a number of potential obstacles, including the administrative challenges from having to harmonize LCDs among eleven MACs, implications for beneficiary appeal rights and related administrative burden for the MACs, and states' scope of practice laws.

The CMS believes that our continued engagement with the MACs as described above, particularly the work of the LCD Writers Workgroups will lead to the development of appropriate, evidence-based LCDs and increased LCD consistency where appropriate.

The CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office; Kenneth Price, Deputy Regional Inspector General; and Russell Hereford, Deputy Regional Inspector General.

Tim Chettiath served as the lead analyst for this study. Central office staff who provided support include Clarence Arnold, Scott Manley, and Christine Moritz.

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